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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,186	04/04/2005	Kazuhiro Saito	074129-0519	5576

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EXAMINER	
TELLER, ROY R	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/530,186	**Applicant(s)** SAITO ET AL.	
	Examiner Roy Teller	**Art Unit** 1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 January 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112/2nd paragraph of claim 16.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *16-18 and 20-29*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

4/16/07
ANISH GUPTA
PRIMARY EXAMINER

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-18 and 20-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 19, 20, 23, and 27 of copending Application No.10/498,215. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sustained release composition contains the same lactic acid polymer molecular weight averages, same peptide equivalent and is used to prevent or treat the same diseases .
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's response has been carefully considered but was not found persuasive.
Applicant contends that the cited references are different from each other because the instant invention is drawn to improving a blood concentration pattern of a GnRH agonist, whereas the cited reference is directed to improving dispersion of one kind of microcapsule. However, the examiner contends that the sustained release composition of the instant invention and the cited reference contain the same lactic acid polymer molecular weight averages, the same peptide equivalent and is used to prevent or treat the saem diseases.

Claims 16-18 and 20-29 are/stand rejected under 35 USC 103(a) for the reasons of record which are restated below.

Claims 16-18 and 20-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al (USPN 6,113,943) in view of Hutchinson (USPN 5,889,110).
The instant invention is drawn to a sustained release preparation comprising a combination of first microcapsules which release a GnRH agonist (or LHRH) for a long term and second microcapsules which release a GnRH agonist (or LHRH) for a short term.
Such compounds having GnRH activity include, specifically, leuprorelin, buserelin and goserelin, see, i.e, for example, specification, page 2, lines 2-4.
Okada teaches a sustained release preparation comprising a polymer of lactic acid having an average molecular weight of about 25,000 to about 60,000 and a physiologically active peptide, wherein the peptide is leuprorelin, leuprorelin acetate, buserelin or goserelin, and which releases the physiologically active substance over a period of at least five months, see, ie., abstract, column 1-2, claims 1 and 11.
Okada discloses when the physiologically active substance is leuprorelin or leuprorelin acetate, a sustained release preparation is useful for diseases such as prostatic cancer and breast cancer, see, i.e., for example, column 20.
Okada does not teach a short term use of the sustained release preparation.
Hutchinson teaches extended release pharmaceutical compositions, which suitable pharmacologically active peptides such as LHRH, leuprorelin, buserelin, and goserelin, see, i.e., for example, abstract, column 2, claim 4 and 14, . Hutchinson discloses experiments for the release of goserelin over relatively short periods of time of 5-7 weeks, see, i.e., for example, column 26. Huttchinson teaches a lactide/glycolide co-polymer having a weight average molecular weight of about 15,000 Da, see, i.e., for example, column 30.
Based upon the beneficial overall teachings provided by Okada with respect to Hutchinson , Hutchinson discloses similar formulations can be manufactured using, in place of goserelin, either leuprorelin or buserelin and continuous release over a relatively long period of time of up to 6 months, see, i.e, for example column 25 and 22. Okada discloses the dose of the sustained release preparation per administration for one month in terms of a physiologically active range, see, i.e, for example, column 20.
From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's response has been carefully considered but was not found persuasive.
Applicant contends that the cited references are directed to a single preparation. However, the examiner contends that based upon the beneficial overall teachings provided by Okada with respect to Hutchinson, Hutchinson discloses similar formulations can be manufactured using, in place of goserelin, either leuprorelin or buserelin and continuous release over a relatively long period of time of up to 6 months, see, i.e., for example, column 22 and 25. Okada discloses the dose of the sustained release preparation per administration for one month in terms of a physiologically active range, see, i.e, for example, column 20. Applicant contends that the cited prior art has no showing of a blood concentration pattern or a release pattern. However, the examiner contends that Okada's sustained release preparation and Hutchinson's extended release composition disclose a release pattern over a period of time.